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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/050,726	01/16/2002	Marie Sudam Pathirana	60795-A/JPW/ADM/PL	7720

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EXAMINER	
O HARA, EILEEN B	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 12/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/050,726	PATHIRANA, MARIE SUDAM	
	Examiner	Art Unit	
	Eileen O'Hara	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2 and 3* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2 and 3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *1/16/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 2 and 3 are pending in the instant application. Claim 2 has been amended and claim 3 has been added as requested by Applicant in the Preliminary Amendment Paper filed Jan 16, 2002.

Priority

2. Applicant is reminded of the following requirement:

In a continuation or divisional application (other than a continued prosecution application filed under 37 CFR 1.53(d)), the first sentence of the specification or application data sheet (37 CFR 1.76) should include a reference to the prior application(s) from which benefit of priority is claimed, and also the status. See 37 CFR 1.78. The status of application 09/466,570 should be updated (now abandoned).

Claim Rejections - 35 USC § 101 and § 112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 2 and 3 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claims 2 and 3 are directed to polynucleotides comprising the nucleotide sequence of SEQ ID NO: 1, that encode the polypeptide comprising the amino acid sequences of SEQ ID NO:2. The instant specification discloses that the polypeptide comprising the amino acid sequences presented in SEQ ID NO: 2 and identified as human SNORF68 receptor, is

presumably a member of the G-protein coupled receptor family, based on homology to that family of proteins, and is an "orphan" GPCR because the endogenous ligand is not known. However, the nucleic acids or encoded protein do not have a specific, substantial or well established utility. Applicant is directed to the Utility Examination Guidelines, Federal Register, Vol. 66, No. 4, pages 1092-1099, Friday, January 5, 2001.

The instant application states that the nucleic acid molecules can be used as probes to obtain homologous nucleic acids from other species and to detect the existence of nucleic acids having complementary sequences in samples, to express the protein it encodes, and to enable further elucidation of possible receptor diversity and of the existence of multiple subtypes within a family of receptors of which SNORF68 is a member. The specification further states that the SNORF68 receptor can be used to discover the endogenous ligand, to screen for agonists, antagonists or compounds that bind to it.

However, these are not considered to be specific or substantial utilities for either the nucleic acid molecule or the protein, as based on the utility guidelines. The methods such as recombinant production of protein and probing for similar nucleic acids are considered general methods, and are not considered to be specific or substantial utilities. It is asserted that the SNORF68 polypeptide is a receptor in the GPCR family. There is no ligand identified that binds to it, no signaling pathway with which it is involved, and no disease or disorder correlated with the polypeptide. The use of an orphan receptor to discover its ligand or properties does not constitute a specific, substantial utility. The assertion that the nucleic acids or protein of the instant invention can be used in discovering drugs for diagnosing or for treating various pathophysiological diseases or disorders is also not a specific and substantial utility, and it based

on the protein being a member of the G protein-coupled receptor superfamily, which as a family are involved in myriad biological pathways, activities and disorders. Many proteins are members of evolutionarily related families, yet have diverse biological activities and functions. The members of the G-protein coupled receptor family bind distinct ligands, are expressed in different tissue and cell types and have specific biological activities. In the minireview of Ji et al., The Journal of Biological Chemistry, Vol. 273, No. 28, July 1998, pages 17299-17302, it is taught that the G protein-coupled receptor superfamily contains nearly 2000 members, which have the same basic structure, but are divided into subfamilies that bind different types of ligands, such as the biogenic amine receptors, nucleoside and nucleotide receptors, eicosaniod receptors, glycoprotein hormone-releasing hormone receptors, glucagons, calcitonin, vasoactive intestinal peptide receptors, parathyroid hormone receptors, protease activated receptors, glycoprotein hormone receptors and neutotransmitter receptors. Gershengorn and Osman, Endocrinology, Minireview: Insights into G Protein-Coupled Receptor Function Using Molecular Models, Vol. 142, No. 1, pages 2-10, also teach that the GPCRs represent the largest family of signal-transducing molecules known, and that they convey signals for light and many extracellular regulatory molecules such as hormones, growth factors and neutotransmitters, that regulate every cell in the body. Though the protein of the instant invention may be classified as a member of the GPCR superfamily, this does not automatically confer a specific and substantial utility to the protein, since there is extreme diversity in the activities and biological functions of these receptors.

The specification further asserts that the molecules of the invention can be used as a tool for designing drugs for treating various pathophysiological conditions such as arthritis, AIDS,

dementia, obesity, stroke, cancers, and a number of other diseases or disorders listed in the paragraph bridging page 6 and 7, and diagnostically in assays for such conditions. However, there is no nexus disclosed between the molecules of the invention and any diseases or disorders. In the preliminary amendment to the specification filed Jan. 16, 2002, results from quantitative PCR results show that SNORF68 mRNA levels are high in testes, and relatively lower levels are seen from other tissues (Table 1). From this data, the specification asserts that the DNA encoding the human SNORF68 receptor can be used to predict the likelihood that a tissue sample of unknown origin is of testes origin with respect to a given individual. This is also not a specific and substantial utility, as other genes are that highly expressed in testes could be used for the same purpose. It is further asserted that the SNORF68 DNA could be used to detect tumor metastasis; however there is no evidence that SNORF68 is expressed in metastasizing tumors, so that this is also not a specific and substantial utility. Since the instant specification does not disclose any specific and substantial utility for the SNORF68 receptor, there is accordingly no utility for nucleic acids encoding the polypeptide. It is possible that, after further characterization, this protein might be found to have a patentable utility, in which case the nucleic acids would have a specific utility, or the protein might be found to be associated with a specific disease.

In Brenner v. Manson, 148 U.S.P.Q. 689 (Sus. Ct,.1966), a process of producing a novel compound that was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be useful because the compound produced thereby was potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad

interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The instant claims are drawn to a polynucleotide encoding a protein which has undetermined function or biological significance. Until some actual and specific activity can be attributed to the proteins identified in the specification as SNORF68 receptor, or the polynucleotide encoding it, the claimed invention is incomplete.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4.1 Claims 2 and 3 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

4.2 Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants referral to the deposit of plasmid pEXJ.T3T7-hSNORF68-f (ATCC Patent Deposit Designation No. PTA -1041) on page 5 of the specification is an insufficient assurance that all of the conditions of 37 CFR sections 1.801 through 1.809 have been met. If the deposits were made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicants, assignees or a statement

by an attorney of record over his or her signature and registration number stating that the deposits have been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposits will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves these specific matters to the discretion of each State. Additionally, amendment of the specification to recite the date of the deposit, the complete name and address of the depository, and the accession number of the deposited cell line is required.

Priority Determination

35 U.S.C. § 120 states that:

> An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States, or as provided by section 363 of this title, which is filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application.

5. Applicant is advised that the instant application can only receive benefit under 35 U.S.C. § 120 from an earlier application which meets the requirements of 35 U.S.C. § 112, first paragraph, with respect to the now claimed invention. Because the instant application does not meet the requirements of 35 U.S.C. § 112, first paragraph, for those reasons given above and it is a continuation in part of application Serial Number 09/466,570, the prior application does not meet those requirements and, therefore, is unavailable under 35 U.S.C. § 120. The effective

priority date of the instant application is considered to be the filing date of this application, Jan. 16, 2002, because the claimed invention is not supported by either a specific and substantial utility or a well established utility.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 2 and 3 are rejected under 35 U.S.C. 102(e) as being anticipated by Lal et al., WO 01/98351, Dec. 27,2001, priority date July 7, 2000 (60/216,595).

Claims 2 and 3 encompass a recombinant nucleic acid comprising a nucleic acid encoding a SNORF68 receptor having the amino acid sequence of SEQ ID NO: 2 or encoded by plasmid pEXJ.T3T7-hSNORF68-f.

Lal et al. disclose a nucleic acid molecule (SEQ ID NO: 1) that is 100% identical to nucleotides 26-1536 of SEQ ID NO: 1, which encodes a protein (SEQ ID NO: 2) that is 100% identical to the protein of SEQ ID NO: 2 of the instant invention. Therefore, Lal et al. anticipates the claims.

Conclusion

7. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

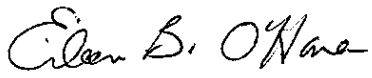
Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.



Patent Examiner